

REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed August 15, 2003 ("Office Action"). Applicant respectfully requests reconsideration of the rejections of claims 72-76, 79-88, 90-92, 95-98 and 101-119 for at least the following reasons.

Submitted herewith is a Petition for Unintentionally Delayed Claim for Benefit of Prior Filed Application Under 37 C.F.R. § 1.78(a) and a newly executed Inventor Declaration.

STATUS OF THE CLAIMS

Claims 72-119 are pending in the application.

Claims 72, 74, 77, 82-83, 89-91, 93-102, 104, 107-108, 112, 114, 117-118 are amended.

No new matter is added by these amendments.

OBJECTION TO THE SPECIFICATION

The specification has been amended to address the Examiner's objection in paragraph 3 of the Office Action concerning the Brief Description of the Drawings.

CLAIM OBJECTIONS

Claims 77-79, 89, 93, 94, 99 and 100 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 77, 89, 93, 99, and 100 have been rewritten in independent form. Claims 78-79 and 94 depend from claims 77 and 93, respectively. Accordingly claims 77-79, 89, 93, 94, 99 and 100 are believed to be allowable.

REJECTIONS UNDER 35 U.S.C. § 112

With respect to the Examiner's rejection under 35 U.S.C. § 112, paragraph 2, claim 96 has been amended to depend from claim 95, which recites a hydrophobic coating. Claim 95

provides proper antecedent basis for the hydrophobic coating recited in claim 96. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 102

The Office Action has rejected claims 72-74, 82-85, 90, 97, 101, and 103-116 under 35 U.S.C. § 102(e) as allegedly being anticipated by Eppstein (U.S. Patent No. 5,722,397). That rejection is respectfully traversed.

Eppstein discloses a method for determining the concentration of an analyte in the body by enhancing the permeability of the skin with a chemical enhancer, applying ultrasound energy that further induces a local pressure gradient out of the body, collecting the analyte, and, utilizing the analyte collection data, calculating the concentration of the analyte in the body. *See* Abstract. The ultrasound energy can be used with modulations of frequency, intensity and/or phase to controllably push and/or pump molecules through the stratum corneum. By modulating the intensity, frequency and/or phase of the ultrasound energy, the transdermal flux rate can be regulated. *See* col. 5, lines 14-21. The time during which the ultrasound energy is to be applied will vary somewhat depending upon the specific means of application. Without the use of chemical enhancers the times required will be longer. When using chemical enhancers to penetrate the stratum corneum making it more susceptible to analyte withdrawal the time period can be shortened significantly. *See* col. 6, line 64 - col. 7, line 3. It is the combination of ultrasound accompanied by the use of chemical enhancers that result in the improved rate of analyte withdrawal through the stratum corneum. *See* col. 11, lines 51-53.

Eppstein does not disclose or suggest both (a) increasing a permeability level of an area of skin by applying low frequency ultrasound forces to said area and (b) extracting said at least one analyte through said area of skin by application of a transport force to said area. Rather, in

Eppstein, the ultrasound is used to extract the analyte and the chemical enhancer is used to increase the permeability of the skin. Note in Example 1 of Eppstein, that after the application of ultrasound without chemical enhancers, no visual indication of dye flux across the stratum corneum was observed.

Eppstein also does not disclose or suggest continuously determining the quantity of the at least one analyte in the body fluid in the sensing zone, as recited in claim 72. By contrast, in Eppstein, a collection reservoir, such as a filter paper or membrane, is removed and transported to another analyzer for analysis. *See* col. 6, lines 6-8.

For the foregoing reasons, Applicants respectfully submit that Eppstein cannot properly form the basis for a rejection of claim 72 under 35 U.S.C. § 102(e).

With respect to claim 107, this claim recites both (a) a low frequency ultrasound transducer for increasing the permability of an area of skin, and (b) means providing an extraction transport force through said area. As discussed above, Eppstein does not disclose or suggest this claimed combination of features. Rather Eppstein discloses ultrasound used to extract the analyte and a chemical enhancer used to increase the permeability of the skin. Eppstein also does not disclose a sensing device in said sensing zone for continuously measuring the quantity of said at least one analyte in said body fluid. Rather, in Eppstein, a collection reservoir, such as a filter paper or membrane, is removed and transported to another analyzer for analysis.

For the foregoing reasons, Applicants respectfully submit that Eppstein cannot properly form the basis for a rejection of claim 107 under 35 U.S.C. § 102(e).

Claims 73-74, 82-85, 90, 97, 101, 103-106, and 108-116 all depend directly or indirectly from either claim 72 or claim 107. These claims are therefore allowable for at least the same

reasons that claims 72 and 107 are allowable. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

On page 5 of the Office Action, claims 72-74, 80-82, 88, 90-92, 97, 98 and 102 were rejected under 35 U.S.C. § 102(e) based on U.S. Patent 5,947,921 ("Johnson"). This rejection is respectfully traversed.

Johnson discloses methods for drug delivery and measurement of analyte using ultrasound in combination with chemical and/or physical enhancers of transport. *See* col. 1, lines 6-9. In one embodiment, the compound is an analyte such as glucose which is present in a body fluid and extracted by application of the ultrasound, alone or in combination with other forces and/or chemical enhancers. *See* col. 3, lines 53-56.

Johnson does not disclose or suggest continuously determining the quantity of said at least one analyte in said body fluid in said sensing zone, as recited in claim 72. By contrast, in Johnson, a reservoir or collecting container is applied to the site for collection of the sample, which is then measured using standard techniques. *See* col. 11, lines 17-20. Therefore, Johnson cannot properly form the basis for a rejection of claim 72 under 35 U.S.C. § 102(e).

Claims 73-74, 80-82, 88, 90-92, 97-98 and 102 all depend directly or indirectly from claim 72. These claims are therefore allowable for at least the same reasons that claim 72 is allowable. Accordingly, reconsideration and withdrawal of this ground of rejection are respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103

In paragraphs 10, 11 and 12 of the Office Action, various claims (75-76; 86-87; 95) have been rejected under 35 U.S.C. § 103(a) in view of Johnson in combination with one of three

secondary references (Cunningham, Grace or Aronowitz). The secondary references are cited for their alleged teachings of features recited in the dependent claims. However, none of the secondary references can remedy the deficiencies of Johnson discussed above with respect to claim 72. Therefore, the combination of Johnson with any one of the secondary references cannot render these claims (75-76; 86-87; or 95) unpatentable. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) set forth in paragraphs 10-12 of the Office Action are respectfully requested.

In paragraph 13 of the Office Action, claims 117-119 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Eppstein in view of Johnson. This rejection is respectfully traversed.

With respect to claim 117, neither Eppstein nor Johnson discloses or suggests continuously monitoring a change in said at least one characteristic of said gel. With respect to claim 118, neither Eppstein nor Johnson discloses or suggests a monitoring device for continuously monitoring a change in said at least one characteristic of said gel. The combination of Eppstein with Johnson therefore cannot possibly produce the subject matter of Applicants' claim 117 or claim 118. Claim 119 depends from claim 118, and is therefore allowable for at least the same reasons that claim 118 is allowable. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) set forth in paragraph 13 of the Office Action are respectfully requested.

CONCLUSION

Applicants respectfully submit that this application, as amended, is in condition for allowance, and reconsideration and allowance of the application is respectfully requested. If the

Examiner believes that prosecution might be advanced by discussing the application with Applicant's counsel, in person or over the telephone, we would welcome the opportunity to do so.

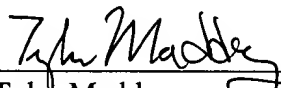
It is believed that no fees are due with this response. However, in the event any other fees are due, the Commissioner is hereby authorized to charge the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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